

## REMARKS

### STATUS OF THE CLAIMS

Claims 17 and 19-23 are pending as shown in the amendment filed with the RCE, received by the Office on April 22, 2004. Applicants note with appreciation that claim 20 is considered allowable.

### REJECTIONS WITHDRAWN

Applicants acknowledge with appreciation that the previous rejections under 35 U.S.C. § 102/103 have all been withdrawn.

### 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 17, 19 and 21-23 were rejected under 35 U.S.C. § 112, first paragraph as allegedly not enabled by the specification as filed. (Office Action, paragraphs 2-11). In particular, it was asserted that the specification did not reasonably enable alphavirus replicons comprising a mutation amino acid positions 158-162 (other than position 160). (Office Action, paragraph 2). In addition, claims 21-23 were also rejected under 35 U.S.C. § 112, first paragraph as allegedly not described in the specification as filed. (Office Action, paragraphs 12-14). Again, it was maintained that the specification does not adequately describe mutations other than that at position 160. *Id.*

Because the Office previously made and subsequently withdrew these same rejections under 35 U.S.C. § 112, first paragraph, Applicants traverse the rejection and supporting remarks.

Applicants remind the Office that it is contrary to basic fairness and public policy for the Office to reintroduce rejections that have been previously withdrawn rejections (*see, e.g.*, M.P.E.P. § 706.07):

To bring the prosecution to as speedy conclusion as possible and at the same time to deal justly by both the applicant and the public, the invention as disclosed and claimed should be thoroughly searched in the first action and the references fully applied; and in reply to this action the applicant should amend with a view to avoiding all the grounds of rejection and objection. Switching from one subject matter to another in the claims presented by applicant in successive amendments, or from one set of references to another by the examiner in rejecting in successive actions claims of substantially the same subject matter, will alike

tend to defeat attaining the goal of reaching a clearly defined issue for an early termination, i.e., either an allowance of the application or a final rejection.

In the pending case, the same rejections, including same references and same case citations, have been addressed multiple times by Applicants and, in fact, were entirely overcome approximately one year ago. On July 27, 2003, Applicants responded to these rejections and, in addition, submitted a Declaration under 37 C.F.R. § 1.132 by John Polo addressing these very points. As stated in the Final Office Action mailed on September 25, 2003, after consideration of the arguments and Declaration, the rejections were withdrawn (see, Office Action mailed 9/25/03, page 2):

#### **Declaration of John M. Polo**

The Declaration under 37 C.F.R. § 1.132 filed on July 28 has been acknowledged. However, it is sufficient to over the 112 1<sup>st</sup> paragraph rejection of claims 17 and 21-23 based upon Dr. Polo's statement that mutation of an amino acid residue in the specified region of amino acid residues 158-162 of alphavirus E2 protein in view of the disclosure of the specification and state of art, a person of skill in the art would surmise that mutations in this region would be much more likely to exhibit DC-tropism by using routine experimentation (see, paragraph 8 on page 3).

Thus, it is improper for the Office to reintroduce rejections that have been overcome. For the reasons of record, including the declaratory evidence previously submitted and found persuasive, Applicants submit that the Office has already deemed the specification as filed to be fully enabling and to adequately describe the subject matter of all the pending claims. Accordingly, the rejection should be withdrawn.

**CONCLUSION**

Applicants respectfully submit that the claims are in condition for allowance. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

Please direct further communication regarding this application to:

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Respectfully submitted,

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